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| 759 | 90 07/19/2002 | | | |
| Stephen A. Bent | | | EXAMINER | |
| FOLEY & LARDNER Washington Harbour | | | DAVIS, RUTH A | |
| 3000 K Street, N.W., Suite 500 Washington, DC 20007-5109 | | | ART UNIT | PAPER NUMBER |
| washington, DC | 2000. 2139 | | 1651 | X |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | Application No. | Applicant(s) | |
| | | 09/813,292 | KRINGELUM E | T AL. |
| Office Action Su | mmary | Examiner | Art Unit | |
| | | Ruth A. Davis | 1651 | |
| The MAILING DATE of | this communication ap | pears on the cover sheet w | vith the correspondence | address |
| ded for Donly | | | | |
| A SHORTENED STATUTOR' THE MAILING DATE OF THIS - Extensions of time may be available un after SIX (6) MONTHS from the mailing. If the period for reply specified above is If NO period for reply is specified above. Failure to reply within the set or extend. Any reply received by the Office later the earned patent term adjustment. See 3 | der the provisions of 37 CFR 1. date of this communication. Iless than thirty (30) days, a reless, the maximum statutory perioded period for reply will, by statution three months after the mailing | 136(a). In no event, however, may a ply within the statutory minimum of the divill apply and will expire SIX (6) MO | a reply be timely filed nirty (30) days will be considered to the mailing date of the ARANDONED (35 U.S.C. § 133) | imely. nis communication. |
| 1)⊠ Responsive to commu | ınication(s) filed on <u>30</u> | April 2002 . | | |
| . 57 mile author to FINAL | 2h)□ 1 | This action is non-final. | | |
| /_ | is in condition for allowith the practice unde | wance except for formal ner Ex parte Quayle, 1935 | natters, prosecution as f C.D. 11, 453 O.G. 213. | o the merits is |
| 4)⊠ Claim(s) 1-26 is/are p | ending in the applicati | on. | | |
| 4a) Of the above claim | (s) is/are withd | rawn from consideration. | | |
| 5) Claim(s) is/are | | | | |
| 6)⊠ Claim(s) <u>1-26</u> is/are re | | | | |
| 7)[7] Claim(s) is/are | objected to. | | | |
| 8) Claim(s) are su | ibject to restriction and | d/or election requirement. | | |
| Application Papers | | | | |
| 9)☐ The specification is ob | jected to by the Exam | iner. | by the Evaminer | |
| 10) The drawing(s) filed or | n is/are: a)∐ ad | cepted or b) objected to | by the Examinor. | 35(a). |
| Applicant may not req | uest that any objection to | the drawing(s) be held in a | disapproved by the E | xaminer. |
| Applicant may not req 11)☐ The proposed drawing | correction filed on | Is: a) approved b) | dioapp. 5 - 5 - 5 , | |
| If approved, corrected | drawings are required in | reply to this Office action. | | |
| 12) The oath or declaration | | Exammer. | | |
| Priority under 35 U.S.C. §§ 1 | 19 and 120 | 1 2511.5 | c s 110(a)-(d) or (f) | |
| 13) Acknowledgment is r | nade of a claim for for | eign priority under 35 U.S | 5.0. 9 1 13(a) (a) 51 (i) | |
| a)∐ All b)∐ Some * | c) None of: | | | |
| 1. ☐ Certified copie | s of the priority docum | nents have been received | :- Application No. | |
| 2. Certified copie | s of the priority docun | nents have been received | In Application No | — · etional Stage |
| application | n from the international | priority documents have bal Bureau (PCT Rule 17.2 a list of the certified copies | s not received. | |
| 141 Acknowledgment is M | ade of a claim for don | nestic priority under 35 U. | S.C. § 119(e) (to a prov | risional application |
| a) ☐ The translation 15) ☐ Acknowledgment is r | continuiting | o provisional anniication i | ISS DECLIFOCIAGE. | |
| Attachment(s) | | | | |
| Notice of References Cited (P' Notice of Draftsperson's Pater Information Disclosure Statem | it Drawing Review (P10-94 | 8) 5) No | erview Summary (PTO-413) F tice of Informal Patent Applica ter: | 'aper No(s) ation (PTO-152) |
| U.S. Patent and Trademark Office | | E Action Cummany | | Part of Paper No. 8 |

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DETAILED ACTION

Applicant's amendment has been received and entered into the case. Claims 25 - 26 have been added. Claims 1 - 26 are pending and have been considered on the merits.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1 26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for supplying a starter culture, however remain vague and indefinite for reciting "using a subset" because it is unclear how this is a step for supplying a starter culture. Moreover, because the language does not set forth any steps involved regarding "using" a subset of stock inoculum, it is unclear what method/process applicant is intending to encompass.

Claim 1 remains confusing for reciting "for a period of time adjusted sufficiently in size".

Applicant may prefer to replace the phrase "adjusted sufficiently in size" with "sufficient" to more clearly point out the claimed invention.

Claim 5 remains vague and indefinite because the claim appears to claim a ratio of CFUs of the subset of stock inoculum after inoculation into the medium : CFUs of the subset of stock

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inoculum being inoculated. However, applicant argues that the claim reflects the ratio of the concentration of the starter culture: the concentration in the culture medium. As the claim appears to indicate a ratio opposite that argued by applicant, it is unclear which ratio applicant intends to encompass.

Claim 7 remains vague and indefinite because the claim still does not specifically point out what the cultivation medium is. It is reiterated that the claim does not contain a transitional phrase and merely states that the medium "may be" any conventional medium. Applicant may prefer to replace the phrase "may be" with the word "comprises" to more clearly point out the claimed invention.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 6-7, 11, 17-22 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Sing.

Applicant argues that Sing does not teach the method wherein a subset of the stock inoculum is used to inoculate the medium, but that the entire stock inoculum is used. Applicant additionally argues that Sing does not teach harvesting the propagated cells wherein they can be used as additional starter cultures. Finally, applicant argues that the claimed method reduces contamination and variation of cell cultures.

However, these arguments fail to persuade because while Sing does not specifically teach using only a portion of the stock inoculum, Sing does teach inoculating the culture medium with at least 10^9 CFU/g (which is at least 10^8 CFU/g as claimed). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to take a portion of a stock material when following the methods of Sing, such that the disclosed amount is inoculated into the culture medium. Moreover, at the time of the claimed invention one of ordinary skill in the art would have been motivated to inoculate a subset of a stock inoculum, with a reasonable expectation for propagating cells and harvesting the propagated cells. In addition, Sing specifically teaches that the harvested cells are inoculated into a milk to produce dairy products (or are used as the starter culture). Although Sing does not teach the harvested cells can be divided into several new starter cultures, it would been obvious to one of ordinary skill in the art to do so, since such methods were known in the art for making starter cultures. In addition, it is

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pointed out that the claims merely state, "which subset thereof <u>can be</u> used as said starter culture" (emphasis added). The claims do not explicitly require the harvested cells to be divided and used to provide multiple, additional, new starter cultures, therefore the argument is not commensurate is scope with the claim language.

Finally, in response to applicant's argument that the claimed method reduces contamination and variation of the cell cultures, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

For the reasons stated above and those made previously of record, the claims are rendered obvious over Sing et al.

6. Claims 1, 7 and 25 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Czulak.

7. Claims 1 and 8 – 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Lizak.

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Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Lizak.

8. Claims 1 and 12 – 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Vandenbergh and Matsumiya.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Vandenbergh and Matsumiya.

9. Claims 1 and 17 – 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak and Lizak.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Czulak and Lizak.

10. Claims 1, 20 and 22 – 23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Rimler and Lizak.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Rimler and Lizak.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad July 16, 2002

> YEON B. LANKFORD, JR. PRIMARY EXAMINER